

# Comparison of the Teno Fix Tendon Repair System and a standard suture repair in Zone II flexor tendon lacerations of the hand.

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 26/04/2011	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

N0013145917

# Study information

## Scientific Title

### Study objectives

Is there a reduced rupture rate and improved outcome using the Teno Fix Tendon Repair System in comparison to a standard suture repair in zone II flexor tendon lacerations in the hand?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

## Participant information sheet

### Health condition(s) or problem(s) studied

Injury, Occupational Diseases, Poisoning: Tendon lacerations

### Interventions

Randomisation of adult patients with zone II flexor tendon lacerations to receive either the Teno Fix repair or standard suture repair. Assessment of outcomes by blinded, independent observer.

Added 29 July 2008: trial stopped in 2006 due to poor recruitment.

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

Tendon rupture rate and digital range of motion at 12 weeks post-repair.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/03/2003

**Completion date**

01/09/2003

**Reason abandoned (if study stopped)**

Poor recruitment

## Eligibility

**Key inclusion criteria**

Adult patients with acute Zone II flexor tendon lacerations in the hand.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

50

**Key exclusion criteria**

1. Adults above 60 yrs of age
2. Flexor tendon lacerations outside Zone 2
3. Complex injuries, eg crush, mutilation, skin loss, amputations, revascularisation
4. The presence of established infection in injured hand
5. Associated digital fractures
6. Delayed surgery
7. Severe intercurrent medical illness
8. Drugs, eg immunosuppressives, steroids, which can affect healing
9. Previous injuries to affected hand
10. Pre-existing arthritis in affected hand
11. Allergy to metals in the stainless steel suture of Teno Fix (chromium, copper, cobalt, nickel, iron)

**Date of first enrolment**

01/03/2003

**Date of final enrolment**

01/09/2003

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

#### **Plastic Surgery**

London

United Kingdom

SE1 7EH

## **Sponsor information**

### **Organisation**

Department of Health

### **Sponsor details**

Richmond House

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dhmail@doh.gsi.org.uk

### **Sponsor type**

Government

### **Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Guy's and St. Thomas' NHS Foundation Trust (UK) Own account

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration